Canadian Patents Database

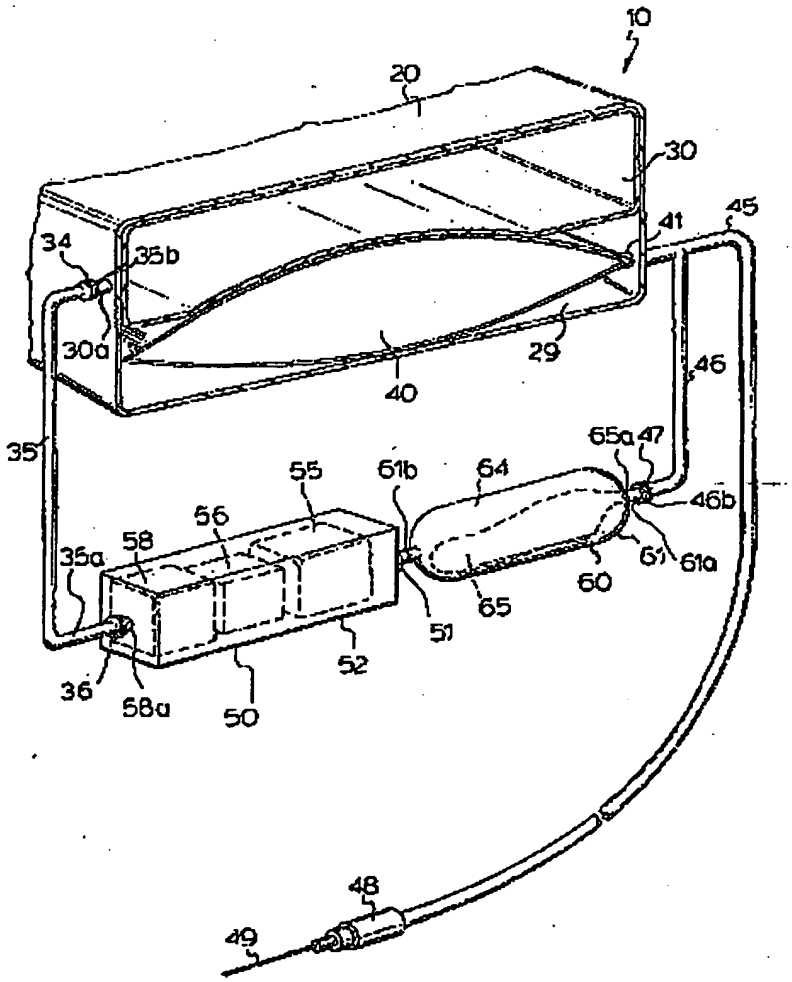
11/19/2002 - 21:40:00

(12) **Patent Application:** (11) **CA 2083555**

(54) PORTABLE INFUSION DEVICE

(54) INFUSEUR PORTABLE

Representative Drawing:



View or Download Images

ABSTRACT:

ABSTRACT
An infusion device including a ridged accessible housing, a flexible air bag contained within the ridged housing in use, a space next to the flexible air bag for containing a drug bag in use, a first line connected to the air bag, a second line connected to the drug bag and patient in use, and a third line connected to the second line, a pumping device connected to the air bag, an electronic control unit for controlling the operation of the pump, a sensing device in communication with the third line, a mechanism for sampling the pressure in the third line and providing the signal to the sensing device without contaminating the medicament in the line to the patient, and an isolation device isolating the sensing device and the third line; wherein a pressure signal from the second line is provided on a constant basis, the electrical control unit communicating with the pump to pump up the air bag as required, when the pressure in the line passes below a predetermined set level in the electronic control unit.

CLAIMS: Show all claims

*** Note: Data on abstracts and claims is shown in the official language in which it was submitted.

(72) Inventors (Country):	**LAING, David H. (Canada)**
(73) Owners (Country):	**LAING, David H. (Canada)**
(71) Applicants (Country):	**LAING, David H. (Canada)**
(74) Agent:	**IVOR M. HUGHES**
(45) Issued:	
(22) Filed:	**Nov. 23, 1992**
(43) Laid Open:	**May 24, 1994**
(51) International Class (IPC):	**A61M 5/148**

Patent Cooperation Treaty (PCT): **No**

(30) Application priority data: **None**

Availability of licence:	**N/A**
Language of filing:	**English**

View or Download Images :

- (•) Cover Page Image
- ( ) Abstract Image
- ( ) Claims Image
- ( ) Disclosures Image
- ( ) Drawings Image
- ( ) Representative Drawing Image

Consommation et Corporations Canada
Bureau des brevets

Consumer and Corporate Affairs Canada
Patent Office

Ottawa, Canada
K1A 0C9

(21) (A1) 2,083,555
(22) 1992/11/23
(43) 1994/05/24

5,090,054

(51) INTL.CL.[5] A61M-005/148

(19)(CA) **APPLICATION FOR CANADIAN PATENT** (12)

(54) Portable Infusion Device

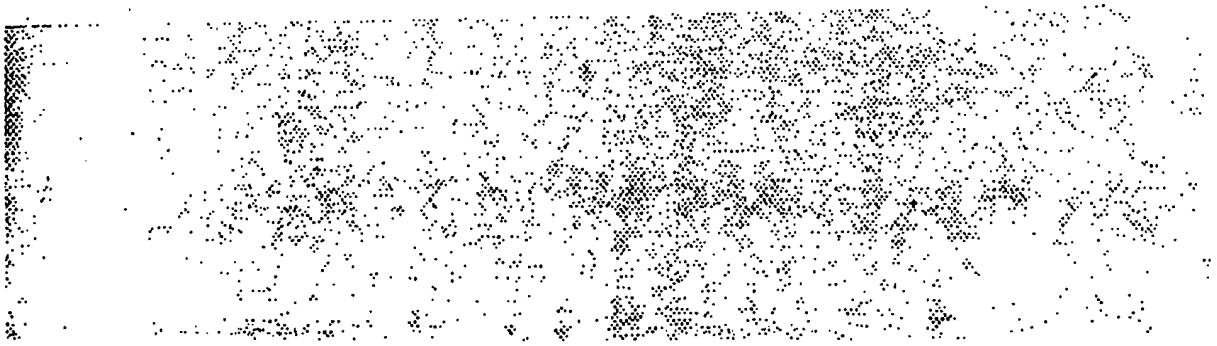
(72) Laing, David H. - Canada ;

(73) Same as inventor

(57) 22 Claims

Canada

CCA 3254 (10-89) 41



ABSTRACT

2083555

An infusion device including a ridged accessible housing, a flexible air bag contained within the ridged housing in use, a space next to the flexible air bag for containing a drug bag in use, a first line connected to the air bag, a second line connected to the drug bag and patient in use, and a third line connected to the second line, a pumping device connected to the air bag, an electronic control unit for controlling the operation of the pump, a sensing device in communication with the third line, a mechanism for sampling the pressure in the third line and providing the signal to the sensing device without contaminating the medicament in the line to the patient, and an isolation device isolating the sensing device and the third line; wherein a pressure signal from the second line is provided on a constant basis, the electrical control unit communicating with the pump to pump up the air bag as required, when the pressure in the line passes below a predetermined set level in the electronic control unit.

TITLE OF INVENTION

Portable Infusion Device

FIELD OF INVENTION

This invention relates to portable infusion devices for precise administering of medicaments to patients and finds particular application to portable devices.

BACKGROUND OF THE INVENTION

It is known in the art to provide structures which transfer the fluid or medicament from a drug bag into a line leading to a catheter.

For example, Australian Patent Application 580,184 to the IMED Corporation published May 28, 1987 purports to teach such a device which includes a pump section, as best seen in the drawing, and a strain gauge which is used for a sensing indirectly the fluid pressure in a line. A controller is provided which is quite common in most systems today. The straining of the wire in the strain gauge, is converted from an analog measurement which requires an analog digital conversion in the microprocessor and this is compared to pre-set values in the program of the unit. However, this reference does not refer to the use of an air pump to pump up a flexible air bag (or other motivation such as a spring biased plate) which provides pressure on a drug bag, and there is no reference other than the strain gauge to a fluid pressure sensor but in no way provides the isolation of the sensing means from the fluid being pumped.

Referring to the PCT Application No. WO 90/07942 to the Institute of Biocybernetics published July 26, 1990 purports to teach the use of a volumetric pump for insulin administration including a control unit, an electronic measuring unit, and a measuring element in the outlet catheter which measures the actual pressure of delivery in the catheter. This reference relates to the actual pressure, being measured. From the description however, there is not clear cut definition of the sensor (1) in the drawings, to anything

more than a unit to sense the operation of the pump via analog signals, wherein the pumps ability to pump in relation to these analog signals would be pre-calibrated, based on peak values and zero values, and that a controller would be provided to convert the analog signal to a digital signal. Other than this reference, there is no discussion in the International Application as to the type of device that the sensor might be. Specifically on page 7, it appears that the measuring element is used to monitor the the resistance to the liquid flow, which ultimately is converted from a analog signal to a digital signal for the controller. This is a very general description and in no way provides the isolation of the sensing means from the fluid being pumped.

Canadian Patent Application No. 2,021,284 to Infusaid Inc. and published January 19, 1991 purports to teach a pressure actuated drug delivery device, which as best seen in figure 1, includes a section (16) where the drug is contained and a section (20) where air pressure motivates the drug in the bellows to the catheter. The material passes through a regulator as seen in figure 2, and based on the pressure differential across a thin membrane, the flow will open up or close down. A pressure differential is therefore available to be sensed across the regulator. This reference relates to the use of air pressure to motivate drug delivery. However, this system is implanted, and not something that is worn externally by a user and in no way provides the isolation of the sensing means from the fluid being pumped.

Canadian Letters Patent 1,224,101 purports to teach an implantable device which uses a solenoid pump arrangement as best seen in figure 1, with an outlet flow restriction connected between the pumping chamber and the catheter and an absolute pressure transducer is included in the implantable device, the pressure transducer for measuring the bodies pressure and not the pressure of the fluid. It is interesting to note that check valves are also provided with the solenoid pump in this device.

United States Patent 4,670,006 to Sinnett et al issued June 2, 1987

purports to teach an infusion device, including a housing, an electrically operated fluid pump, a pressure regulator, a first pressure detecting means for detecting the fluid pressure in a conduit, and second pressure detecting means for detecting the fluid pressure in another conduit, and means to pick up the signals from the pressure detecting means for a visual readout, and for driving the motor control unit. In the preferred embodiment the pressure is displayed in millimeters of mercury, as detected by the under pressure transducer 150 and the over pressure detection 160 which is connected to the infusion pressure transducer 100 and an alarm circuit 162. The pump is turned on automatically, if the fluid delivery pressure is less than predetermined level, as detected by the pressure transducer 150 mounted on the front panel of the unit upstream of the pressure regulator, which provides an electrical signal representative of the pump output pressure. In this sense the pump is used for actually pumping the fluid and for not pumping up the air bag, as it is with the present application but in no way provides the isolation of the sensing means from the fluid being pumped.

United States Patent 4,998,914 to Weist et al issued March 12, 1991 purports to teach a procedure including a medical instrument which includes a pump, a pressure sensor, and an electronic system which may include a pressure transducer for determination of the actual fluid pressure in the body cavity. This reference has some similarities with the present invention but lacks the isolation of the sensing means from the fluid being pumped.

U.S. Patent 4,443,218 to Infusaid Corporation which issued April 17, 1984 purports to teach an implantable device controllable by microprocessor including a control fluid circuit motivated by a spring loaded by an electric motor and an infusate circuit. If the control fluid pressure is to low as indicated by the pressure differential reading at 66 the processor issues a command to the motor control circuit at 86. However no pressure reading is

being taken from the infusate.

PCT Application WO 87/05225 to Kamen published September 11, 1987 purports to teach a pressure measurement device for fluid dispensing systems. The application describes the measurement of the Tp 15 as seen in the figures which relates to the pressure at volume 16 and not to the first fluid.

Other examples of similar structures are found in the following documents:

U.S. Patent 4,557,726 to Consolidated Controls Corporation issued December 10, 1985;

U.S. Patent 4,976,162 to Kamen issued December 11, 1990;

European Patent Application 277,518 to Melsungen published August 10, 1988;

U.S. Patent 4,966,579 to Fresenius AG issued October 30, 1990;

U.S. Patent 4,267,834 to American Hospital Supply Corporation and issued May 19, 1981; and

U.S. Patent 4,077,405 to Siemens issued May 7, 1978.

U.S. Patent 5,059,182 issued October 22, 1991 to the present inventor describes an infusion device which includes an extendible container for the pressure medium to pump the infusate wherein the pressure of the pressure medium is 5 times that of the infusate being pumped. No measuring of the actual infusate pressure is provided and hence no isolation of a sensing means from the fluid being pumped.

Finally U.S. Patent 4,504,267 to Parmelee purports to teach an apparatus for intravenous injections and a carrier therefore in the form of a vest like garment.

Nowhere within the prior are is there found an infusion device which overcomes many of the disadvantages of the prior art and provides an infusion device which is preferably portable and includes a pressure

monitoring loop for the infusate pressure which is isolated from the infusate to prevent contamination thereof yet still provide precise administration of a medicament to the patient.

It is therefore a primary object of the invention to provide an infusion device which is portable and allows for the administration of medicaments to patients without the need to be restricted to a hospital or a clinic once the drug bag is in position in the device.

It is a further object of the invention to provide an infusion device which is safe and reliable to use.

It is yet a further object of the invention to provide an infusion device which includes monitoring of the infusate pressure and means to maintain that pressure at the desired levels.

Further and other objects of this invention will become apparent to those skilled in the art when considering the following summary of the invention and the more detailed description of the preferred embodiments illustrated herein.

SUMMARY OF THE INVENTION

According to one aspect of the invention there is provided an infusion device for fluids comprising a rigid frame or housing (preferably separable into two portions), the frame or housing having disposed therewith when assembled a space wherein is disposed in use a flexible bag previously evacuated of air and filled with a fluid (and preferably a medicament such as a drug bag), the flexible bag having an outlet and having a first tube having two ends (preferably of medical grade vinyl) connected thereto in use for carrying the fluid from the flexible bag proximate one end of the first tube to the distal end of the first tube proximate the patient in use and preferably including a needle inserted under the skin of a patient in use, (preferably the first line having disposed adjacent the needle a preferably replaceable precision glass restrictor to precisely control the flow of fluid to the patient in use); the

housing containing in use means to press the fluid bag and cause flow of fluid through the first line to the patient and preferably the needle (preferably said means to press being a flexible air bag of sufficient size to press the fluid bag over the entire length thereof); the infusion device having means to change (such as increase/decrease) the ability of the means to press the fluid bag, to press the fluid bag (preferably an air pump, to pump air into the flexible air bag), the infusion device having sensing means to sense the pressure of the fluid in the first line (preferably a pressure transducer); the infusion device having control means having set points therewith in use for desired fluid pressure in the first line and in communication with the means to press the fluid bag and to receive sensed fluid pressure from the sensing means and to respond to high/low pressures sensed by activating the means to increase/decrease the ability of the means to press the fluid bag to press the fluid bag, a second line (preferably of medical grade vinyl) having two ends and connected with the first line proximate one end of the second line intermediate the ends of the first line, and having disposed proximate the other end of the second line isolation means to present a pressure in the fluid to the sensing means without the sensing means contaminating the fluid being delivered to the patient in use, (preferably the isolation means including an air space in communication with the sensing means and isolated from the fluid in the second line by a flexible impermeable membrane in communication with the fluid of the second line which compresses or decompresses the air space in a direct proportional to the fluid pressure in the second line which pressure is sensed by said sensing means), wherein in use as the fluid bag is pressed fluid passes to the patient through the first line depleting the volume of fluid in the fluid bag, which fluid communicates a pressure in the second line to the isolated sensing means without contaminating the fluid being delivered to the patient, the control means responding to changes in the fluid pressure by activating/deactivating the means to change (such as increase/decrease) the

ability of the means to press the fluid bag to press the fluid bag.

According yet another aspect of the invention there is provided an infusion device for fluids comprising a rigid frame or housing (preferably separable into two portions), the frame or housing having disposed therewith when assembled a space wherein is disposed in use a flexible bag previously evacuated of air and filled with a fluid (and preferably a medicament), the flexible bag having an outlet and having a first tube having two ends (preferably of medical grade vinyl) connected thereto in use for carrying the fluid from the flexible bag proximate one end of the first tube to the distal end of the first tube proximate the patient and preferably including a needle inserted under the skin of a patient in use, preferably the first line having disposed adjacent the needle a preferably replaceable precision preferably glass restrictor to precisely control the flow of fluid to the patient in use; the housing containing in use a flexible air bag having an inlet, and being of sufficient size to press the fluid bag substantially over the length thereof to cause flow of fluid through the first line to the patient and preferably the needle; the infusion device having an air pump in communication with the inlet of the air bag and to pump air into the flexible air bag through the inlet thereof to change (such as increase/decrease) the ability of the air bag to press the fluid bag, the infusion device having a pressure transducer to sense the pressure of the fluid in the first line; the infusion device having electronic control means having set points therewith in use for desired fluid pressure in the first line and in communication with the air pump, and to receive sensed fluid pressure from the pressure transducer and to respond to high/low pressures by activating/deactivating the air pump to pump air into the air bag and change (such as increase/decrease) its ability to press the fluid bag, the infusion device having a second line (preferably of medical grade vinyl) having two ends and connected with the first line proximate one end of the second line intermediate the ends of the first line, and having disposed

proximate the other end of the second line isolation means to present a pressure in the fluid to the pressure transducer without the pressure transducer contaminating the fluid being delivered to the patient in use, the isolation means including an air space in communication with the pressure transducer and isolated from the fluid in the second line by a flexible impermeable membrane (preferably an impermeable membrane sock) in communication with the fluid of the second line which compresses or decompresses the air space in direct proportion to the fluid pressure in the second line which pressure is sensed by, said pressure transducer, wherein in use as the fluid bag is pressed, fluid passes to the patient through the first line depleting the volume of fluid in the fluid bag, which fluid communicates a pressure in the second line to the isolated pressure transducer without contaminating the fluid being delivered to the patient, the electronic control means responding to changes in the fluid pressure by activating/deactivating the air pump to change (such as increase/decrease) the ability of the air bag to press the fluid bag.

In one embodiment the infusion device described in the above paragraphs is contained within a shoulder bag or the like to increase the mobility of the patient. In another embodiment the means to press the fluid bag or the air bag, and the fluid bag are separated within the frame or housing of the infusion device by a hinged moveable plate which assists in ensuring equal pressure is being exerted over the length of the fluid bag.

According to another aspect of the invention there is provided an infusion device comprising a ridged accessible housing, a flexible air bag contained within the ridged housing in use, a space next to the flexible air bag for containing a drug bag in use (and preferably a standard sized drug bag up to 500 cubic centimeters and being flexible), a first line connected to the air bag, a second line connected to the drug bag and patient (preferably with a needle) in use, and a third line connected to the second line, pumping means

connected to the air bag, an electronic control unit for controlling the operation of the pump, sensing means (preferably a pressure transducer) in communication with the third line, means for sampling the pressure in the third line and providing the signal to the sensing means without contaminating the medicament in the line to the patient, and an isolation means isolating the sensing means and the third line; wherein a pressure signal from the second line is provided on a constant basis, the electrical control unit communicating with the pump to pump up the air bag as required, when the pressure in the line passes below a predetermined set level in the electronic control unit.

In a preferred embodiment a restriction may be placed before the needle of the second line for precise administration of the drug. The isolation means to sample the signal from the drug flow line to the patient and yet isolate the pressure sensing means is a crucially important element of the combination presented.

For example, the isolation member may include a sock or diaphragm made from extremely thin flexible impermeable material contained in a chamber attached at one end to the third line and to the sensing means at the other end thereof, the chamber presenting a liquid filled section within the sock or on one side of the diaphragm and an air filled space on the other side of the sock or diaphragm, wherein the flexible sock or diaphragm is contained in the chamber so that in use the fluid acts to produce a pressure reading to the sensing means via the air space on the air side of the sock or diaphragm.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be illustrated with respect to the following drawings illustrating embodiments of the invention in which:

Figure 1 is a side plan schematic view of an infusion device illustrated in a preferred embodiment of the invention.

Figure 2 is a top plan schematic view of the infusion device of Figure 1 illustrated in a preferred embodiment of the invention.

Figure 3 is a schematic view of the another embodiment of an infusion device illustrated in a preferred embodiment of the invention.

Figure 4 is a partially cutaway perspective view of the mechanism described in relation to Figure 3 illustrated in a preferred embodiment of the invention.

Figure 5 is a general perspective view of the use of the infusion device of Figure 4 and illustrated in a preferred embodiment of the invention.

Figure 6 is a circuit diagram for the operation of the control unit of the infusion device and illustrated in a preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Referring now to the figures there is illustrated an infusion device 10 used for administering drugs to a patient. Typically the drug is provided in a pre-packaged flexible container 40 which contains up to 500 cm^2 of medicament to be administered to the patient. One of the advantages of this invention is that it uses standard sized "drug bags" without the need for having to provide special casettes or the like which is found in the prior art. In using a standard drug bag in conjunction with the present invention the Applicant is no longer required to remain sedentary at a hospital or a clinic while the content of the drug bag is administered to the patient.

The infusion device can therefore be provided in a compact ridged housing 20, which offers resistance to the inflation of an air bag 30 made from flexible materials. Disposed below the air bag 30 is a space 29 which is filled substantially in use by the drug bag 40 which is made from flexible material and contains up to 500 cm^2 of the medicament being administered to the patient. The air bag 30 is clamped to a line 35 made of medical grade vinyl and clamped at 34 to a fitting 30(a) provided

with the air bag 30. The line 35 is connected with a diaphragm air pump 58 proximate the other end thereof via a clamp 36.

The drug bag 40 is connected at a tapered end thereof 41 by conventional methods such as a clamp to a section of tubing 45 made of medical grade vinyl which extends to the needle 49 and the patient as best seen in figure 5. Located adjacent the needle 49 is a precision glass restrictor used to precisely control the amount of drug administered to the patient. A detailed description of these precision restrictors is found in my U.S. Patent 5,059,182 and specifically in relation to the detailed description thereof at for example column 7 line 54 onward, which description is hereby incorporated by reference.

In order for the infusion device 10 to be of use to a patient it is important that the housing 20 be separable. No details as to the separation of the housing is provided as it is assumed that those skilled in the art would appreciate the manner in which a housing may be separable into two halfs by a hinge, by telescopic relationship of one half being slightly larger than the other half and inter-fitting with that other half, or one portion being slideable in relation to the other portion. The important aspect is that the housing be rigid and that there be provided access to the hollow space 29 so that a drug bag 40 may be place in the position as shown and affixed to the tubing 45 at clamp 48. Therefore if more than one type of fluid were being administered to a patient sequentially, for example a saline solution followed by a medicament, then the same apparatus may be used and may be easily set up by the nurse or other medical attendant. The clamps 34 and 48 are known to those skilled in the art and therefore no further description is necessary.

A second line 46 in communication with the first line 45 at juncture 46a is provided to allow for a direct pressure reading to be taken from the line 45 as the medicament is delivered to the patient. At

the end 46b of line 46 there is found an impermeable membrane sock 65 contained within an isolation device 60 including a hollow glass receptacle 61 having two ends 61a and 61b. The sock 65 is therefore affixed at the end 61a at end of 65a of the sock with the end of 61a of the glass receptacle. These two portions are therefore clamped to the tube end 46b via clamp 47. Disposed within the isolation device 60 is also an air space 64 which is in communication with the end 61b of the receptacle 61. End 61b is engaged with a control module 50, which includes a transducer 55, by a luer lock fitting. Description of luer lock fittings is found for example in U.S. Patent 4,369,781 assigned to Sherwood Medical Industries Incorporated and describing therein medical luer fittings, the teachings thereof those skilled in the art are referred to for a detailed explanation, such explanation being for a specific luer lock fitting and their parts, function, and use, which description is hereby incorporated by reference. Therefore end 61b of the isolation device 60 is fastened with the control module 50 via luer lock fitting 51 in direct relation with the transducer 55 so that as fluid fills the line 46 and sock 65, the air space 64 will experience a pressure above atmospheric pressure directly proportional to the pressure in the line 45, as the medicament is delivered to the patient. The transducer 55 will therefore have available to it directly the pressure within the section 64. Such reading of pressure will be communicated to the electronic control unit, such as a microprocessor 56, having pre-established set points therewith in relation to the pressure in line 45. Should the pressure therefore in line 45 be below the set point, the microprocessor will communicate with the air pump 58 to pump air from the pump 58 through the line 35 into the air bag 30. The pump 58 is engaged with the air line 35 at end 35a to end 58a of the pump via clamp 36. Also end 35b of the line 35 is engaged with end 30a of the air bag 30

via clamp 34. As the pressure is increased in air bag 30 additional pressure will be exerted by the air bag 30 upon drug bag 40, since the housing 20 containing the air bag 30 is a rigid housing having very little resilience whatsoever resulting in any inflation of the bag 30 being entirely (resilience) exerted upon the drug bag 40 over substantially all of its length. The resulting increased pressure from the air bag 30 will provide an increased velocity of the medicament contained within the drug bag 40 through to the line 45 on to the patient. The resulting increased velocity will result in an increased pressure in the line 45.

It will be appreciated by those skilled in the art that for the infusion device 10 to work correctly it must achieve a stead state so that a substantially constant amount of medicament is being delivered to the patient over a period of time. For example if a drug bag containing 500 cm^2 of liquid is provided and it is desired to deliver this medicament to the patient at the rate of 20 milliliters per hour, (although it is expected for the apparatus the range of 10 milliliters to 100 milliliters per hour to be the expected range of operation), it is also desirable to maintain the delivery of the 20 milliliters per hour uniformly over the 60 minutes represented by the hour. It would not be advantageous to the patient to deliver an extreme amount initially and tapering off to a relatively small amount near the end of the administration cycle. In order therefore to achieve this steady state it is important that the pressure be monitored continually within line 45, and yet the device monitoring the pressure transducer 55, be isolated from contaminating the medicament delivered to the patient, and yet provide readings to the microprocessor to control the flow to the patient within the desired range of deviation. It is therefore desirable for the pressure reading at transducer 55 to be communicated to the microprocessor 56 which in turn compares the pressure reading to set points and based on the difference between the

set point and the reading and whether the difference is positive or negative, will therefore allow the pump 58 to start or prevent it from starting until such time as the difference is negative for example. In this manner therefore a very precise control of the infusion rate can be obtained.

Referring to figures 3 to 5 there is described the identical operation of the infusion device 10a with the exception that the housing 20 of the infusion device is shaped substantially as shown in figure 5 having a top 21a a bottom 23a and hinged member 22a resting between the air bag 30 and the drug bag 40. The purpose of the plate 22a contained within the housing 20 is to provided a more uniform a pressure over the length of the drug bag 40 as the medicament is delivered to the patient. The plat 22a as best seen in figure 4 is pivotally attached via pins 22a1 to the side of housing 20, allowing motion thereof in the directions D1 and D2 as best seen in figure 3. The balance of this operation of the infusion device 10a is consistent with that as previously described, with the exception that in relation to figure 5 the infusion device is provide with a convenience strap as in those manners which those skilled in the art would know. For example an opening may be provide at flange 22b of the housing for the strap to pass there through at both sides of the housing to form a shoulder bag type apparatus A which may be carried by person "P" in an ambulatory fashion thus freeing person "P" from having to be left in a sedentary position at a hospital, taking up a hospital bed and the time of the medical professionals; wherein the medication could equally be administered with the patient "P" going about his or her business at a moderate level of activity around the home for example.

Figure 6 describes one embodiment of many control units that would work with the instant invention. The following description

therefore is for the one specific circuit design to accomplish the necessary tasks for operation of the infusion device. However any electronic circuit or device, or any combination of electronic and pneumatic devices which fundamentally provides set points for the expected pressure within line 45 and a comparison therewith with the actual pressure being read from the line 45. Should the difference between the set point and the actual pressure be positive then the motor will turn on to drive the blower fan to inflate the bag 30 until there is no difference or negative difference. Should the pressure difference between the set point and the actual pressure be negative than the motor will not turn on allowing the pressure in the line 45 to reduce toward the set point.

To accomplish this task therefore the circuit provided in figure 6 as one embodiment only and without limitation provides a transducer model number MPX 52DP which provides two outputs to a linear integrated circuit in chip form which 8 pin chip includes an or gate connected to input pins 2 and 3 and output pin 6 which fires only if output 2 is less than output 4 from the transducer. The input to pin 2 may be reduced in comparison to the value of the output of the transducer by a potentiometer which may be adjusted so as to allow the value of output 2 to be less than the value of output 4. When this is the case the or gate will allow an output on pin 6 which passes through a diode to prevent any reverse current flow which would cause damage to the integrated circuit. Pin 7 is a return pin to the voltage V1 applied to the transducer.

A signal would then carry on through a resister which would then lower the value of the voltage of the circuit passing through to the second linear integrated circuit which is also an 8 pin chip. Input pins 2 and 3 are provided for the or gate and output 6 is provided for the signal

once the or gate f[redacted] The or gate of the second integrate[redacted]rcuit will fire only when the signal from the first integrated circuit is less than the signal resulting from the adjustment of the values of the second set of potentiometers, one of the potentiometers including a diode to prevent reverse current flow thereof and damaging of the second integrated circuit. Therefore when the set points of the two potentiometers of the second integrated circuit are set at certain levels in a manner such that the input to pin 2 will be greater than the input to pin 3 until such a time as the pressure reading in line 45 is less than the set value set via the adjustment provided in the circuitry, the or gate will fire and provide a signal on pin 6 which signal will then be reduced through a silicon controlled rectifier in parallel with an inductor coil which may be for example a meter to obtain a read out convenient to the medical staff or the user so that if the meter is not working the silicon controlled rectifier will not fire since no signal will be provide to the gate of the silicon controlled rectifier. The output of the silicon controlled rectifier will then pass through a transistor at the base thereof which will amplify the signal to a sufficient level to turn on the motor and light the LED to indicate that the motor is turned on when the conditions previously described are present. The fan will than pump up the air bag 30 until such time as the pressure reading in line 45 is above the set point as established by the adjustments in the circuitry and then the silicon controlled rectifier will not fire until such time as the pressure level passes below the set point again.

The above circuit description is provided as an example only and no way limits the variations of circuitry or devices which would work based on advances in technology with the infusion device. It is sufficient that some electronic control unit or combination mechanical, pneumatic and/or electronic be provided which provides the features described

above and the comparison of the set point with the actual pressure readings.

As many changes can be made to the preferred embodiments of the invention without departing from the scope of the invention; it is intended that all material contained herein be interpreted as illustrative of the invention and not in a limiting sense.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE PRIVILEGE OR PROPERTY IS CLAIMED ARE AS FOLLOWS:

1. An infusion device for fluids comprising a rigid frame or housing, the frame or housing having disposed therewith when assembled a space wherein is disposed in use a flexible bag previously evacuated of air and filled with a fluid, the flexible bag having an outlet and having a first tube having two ends connected thereto in use for carrying the fluid from the flexible bag proximate one end of the first tube to the distal end of the first tube proximate the patient in use; the housing containing in use means to press the fluid bag and cause flow of fluid through the first line to the patient; the infusion device having means to change (such as increase/decrease) the ability of the means to press the fluid bag, to press the fluid bag, the infusion device having sensing means to sense the pressure of the fluid in the first line; the infusion device having control means having set points therewith in use for desired fluid pressure in the first line and in communication with the means to press the fluid bag and to receive sensed fluid pressure from the sensing means and to respond to high/low pressures sensed by activating the means to increase/decrease the ability of the means to press the fluid bag to press the fluid bag, a second line having two ends and connected with the first line proximate one end of the second line intermediate the ends of the first line, and having disposed proximate the other end of the second line isolation means to present a pressure in the fluid to the sensing means without the sensing means contaminating the fluid being delivered to the patient in use, wherein in use as the fluid bag is pressed fluid passes to the patient through the first line depleting the volume of fluid in the fluid bag, which fluid communicates a pressure in the second line to the isolated sensing means without contaminating

the fluid being delivered to the patient, the control means responding to changes in the fluid pressure by activating/deactivating the means to change (such as increase/decrease) the ability of the means to press the fluid bag to press the fluid bag.

2. An infusion device for fluids comprising a rigid frame or housing, the frame or housing having disposed therewith when assembled a space wherein is disposed in use a flexible bag previously evacuated of air and filled with a fluid, the flexible bag having an outlet and having a first tube having two ends connected thereto in use for carrying the fluid from the flexible bag proximate one end of the first tube to the distal end of the first tube proximate the patient, the housing containing in use a flexible air bag having an inlet, and being of sufficient size to press the fluid bag substantially over the length thereof to cause flow of fluid through the first line to the patient; the infusion device having an air pump in communication with the inlet of the air bag and to pump air into the flexible air bag through the inlet thereof to change (such as increase/decrease) the ability of the air bag to press the fluid bag, the infusion device having a pressure transducer to sense the pressure of the fluid in the first line; the infusion device having electronic control means having set points therewith in use for desired fluid pressure in the first line and in communication with the air pump, and to receive sensed fluid pressure from the pressure transducer and to respond to high/low pressures by activating/deactivating the air pump to pump air into the air bag and change (such as increase/decrease) its ability to press the fluid bag, the infusion device having a second line having two ends and connected with the first line proximate one end of the second line intermediate the ends of the first line, and having disposed proximate the other end of the second line isolation means to

present a pressure in the fluid to the pressure transducer without the pressure transducer contaminating the fluid being delivered to the patient in use, the isolation means including an air space in communication with the pressure transducer and isolated from the fluid in the second line by a flexible impermeable membrane in communication with the fluid of the second line which compresses or decompresses the air space in direct proportion to the fluid pressure in the second line which pressure is sensed by said pressure transducer, wherein in use as the fluid bag is pressed, fluid passes to the patient through the first line depleting the volume of fluid in the fluid bag, which fluid communicates a pressure in the second line to the isolated pressure transducer without contaminating the fluid being delivered to the patient, the electronic control means responding to changes in the fluid pressure by activating/deactivating the air pump to change (such as increase/decrease) the ability of the air bag to press the fluid bag.

3. The infusion device of claim 1 wherein said means to press the fluid bag is a flexible air bag of sufficient size to press the fluid bag over the entire length thereof.

4. The infusion device of claim 3 wherein said means to change (such as increase/decrease) the ability of the means to press the fluid bag, to press the fluid bag is an air pump, to pump air into the flexible air bag.

5. The infusion device of claim 1, 3 or 4 wherein said sensing means is a pressure transducer.

6. The infusion device of claim 1, 3, or 4 wherein the isolation means including an air space in communication with the sensing means and isolated from the fluid in the second line by a flexible impermeable membrane in communication with the fluid of the second line which compresses or decompresses the air space in a direct proportional to the fluid pressure in the second line which pressure is sensed by said sensing means.

7. The infusion device of claim 5 wherein the isolation means including an air space in communication with the sensing means and isolated from the fluid in the second line by a flexible impermeable membrane in communication with the fluid of the second line which compresses or decompresses the air space in a direct proportional to the fluid pressure in the second line which pressure is sensed by said sensing means.

8. The infusion device of claim 1 or 2 wherein the housing is separable into two portions.

9. The infusion device of claim 1 or 2 wherein the fluid is a medicament.

10. The infusion device of claim 1 or 2 wherein the tubing is made of medical grade vinyl.

11. The infusion device of claim 1 or 2 wherein proximate the patient a needle is inserted under the skin of a patient in use.

12. The infusion device of claim 11 wherein the first line has disposed adjacent the needle a replaceable precision restrictor to precisely control the flow of fluid to the patient in use.

13. The infusion device of claim 2 wherein said impermeable membrane is an impermeable membrane sock.

14. The infusion device of claim 1 or 2 wherein said infusion device is contained within a shoulder bag or the like to increase the mobility of the patient.

15. The infusion device of claim 1 or 2 wherein the means to press the fluid bag or the air bag, and the fluid bag are separated within the frame or housing of the infusion device by a hinged moveable plate which assists in ensuring equal pressure is being exerted over the length of the fluid bag.

16. The infusion device of claim 14 wherein the means to press the fluid bag or the air bag, and the fluid bag are separated within the frame or housing of the infusion device by a hinged moveable plate which assists in ensuring equal pressure is being exerted over the length of the fluid bag.

17. An infusion device comprising a ridged accessible housing, a flexible air bag contained within the ridged housing in use, a space next to the flexible air bag for containing a drug bag in use , a first line connected to the air bag, a second line connected to the drug bag and patient in use, and a third line connected to the second line, pumping means connected to the air bag, an electronic control unit for controlling

the operation of the pump, sensing means in communication with the third line, means for sampling the pressure in the third line and providing the signal to the sensing means without contaminating the medicament in the line to the patient, and an isolation means isolating the sensing means and the third line; wherein a pressure signal from the second line is provided on a constant basis, the electrical control unit communicating with the pump to pump up the air bag as required, when the pressure in the line passes below a predetermined set level in the electronic control unit.

18. The infusion device of claim 17 wherein said drug bag is a standard sized drug bag up to 500 cubic centimeters and being flexible.

19. The infusion device of claim 17 wherein the second line has disposed adjacent the patient a needle.

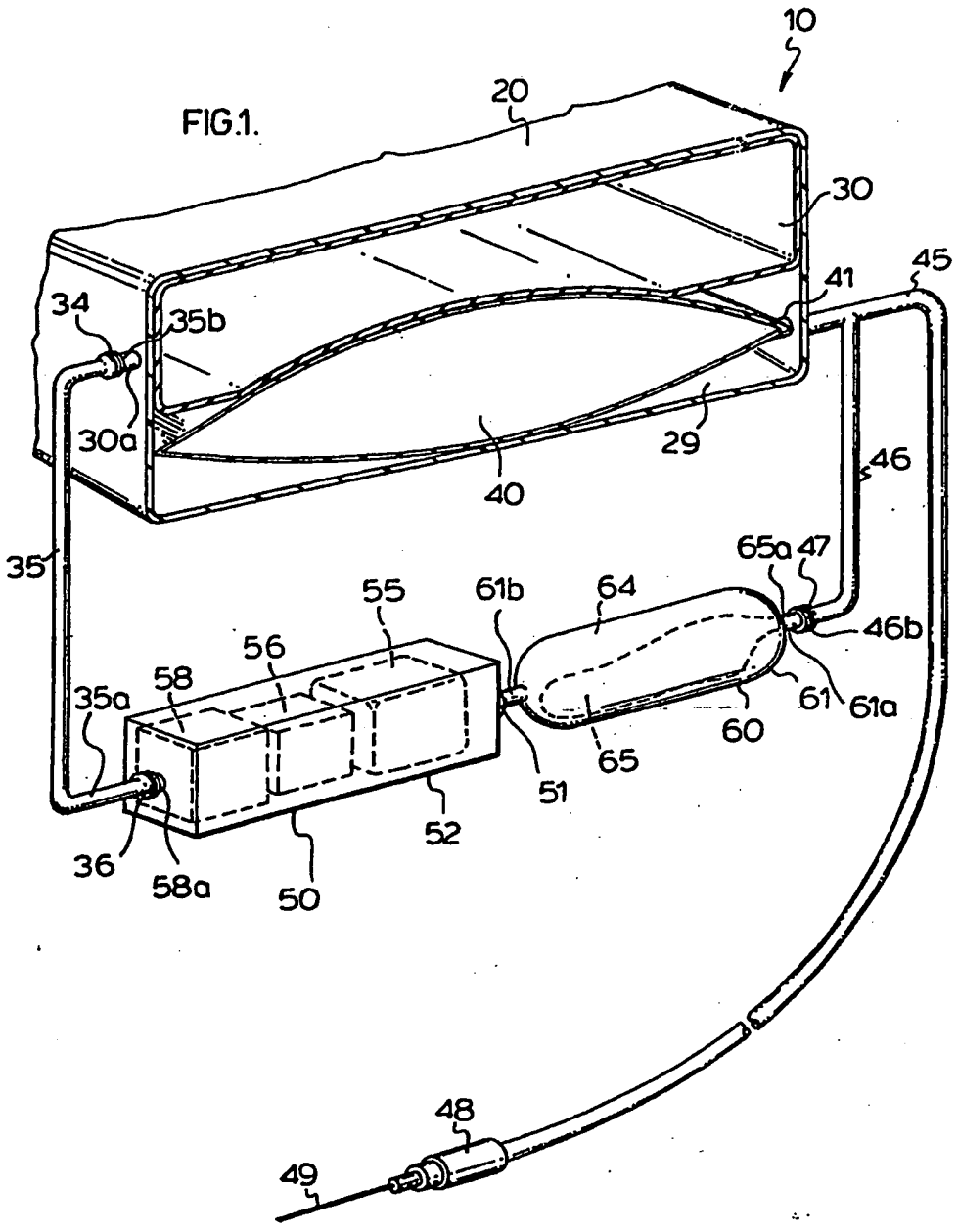
20. The infusion device of claim 17 wherein said sensing means is a pressure transducer.

21. The infusion device of claim 19 wherein a restriction may be placed before the needle of the second line for precise administration of the drug.

22. The infusion device of claim 17, 18, 19, 20, or 21 wherein the isolation member includes a sock or diaphragm made from extremely thin flexible impermeable material contained in a chamber attached at one end to the third line and to the sensing means at the other end thereof, the chamber presenting a liquid filled section within the sock or on one side of the diaphragm and an air filled space on the

other side of the sock or diaphragm, wherein the flexible sock or diaphragm is contained in the chamber so that in use the fluid acts to produce a pressure reading to the sensing means via the air space on the air side of the sock or diaphragm.

FIG.1.


10
20
30
45
41
34
35b
30a
29
40
46
35
65a
47
55
61b
64
46b
56
58
35a
61
61a
60
65
51
52
36
58a
50
48
49

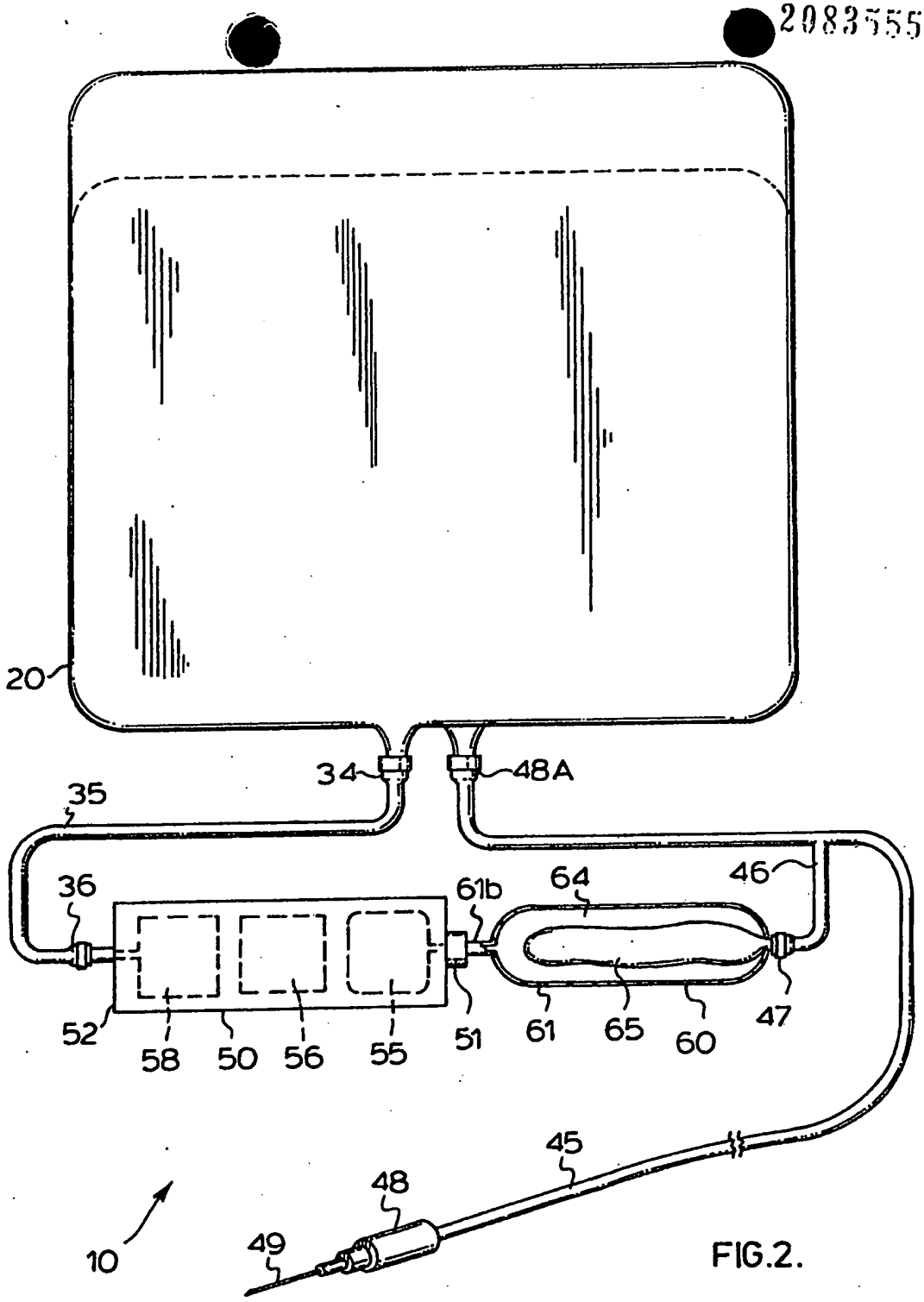


FIG.2.

FIG. 3.

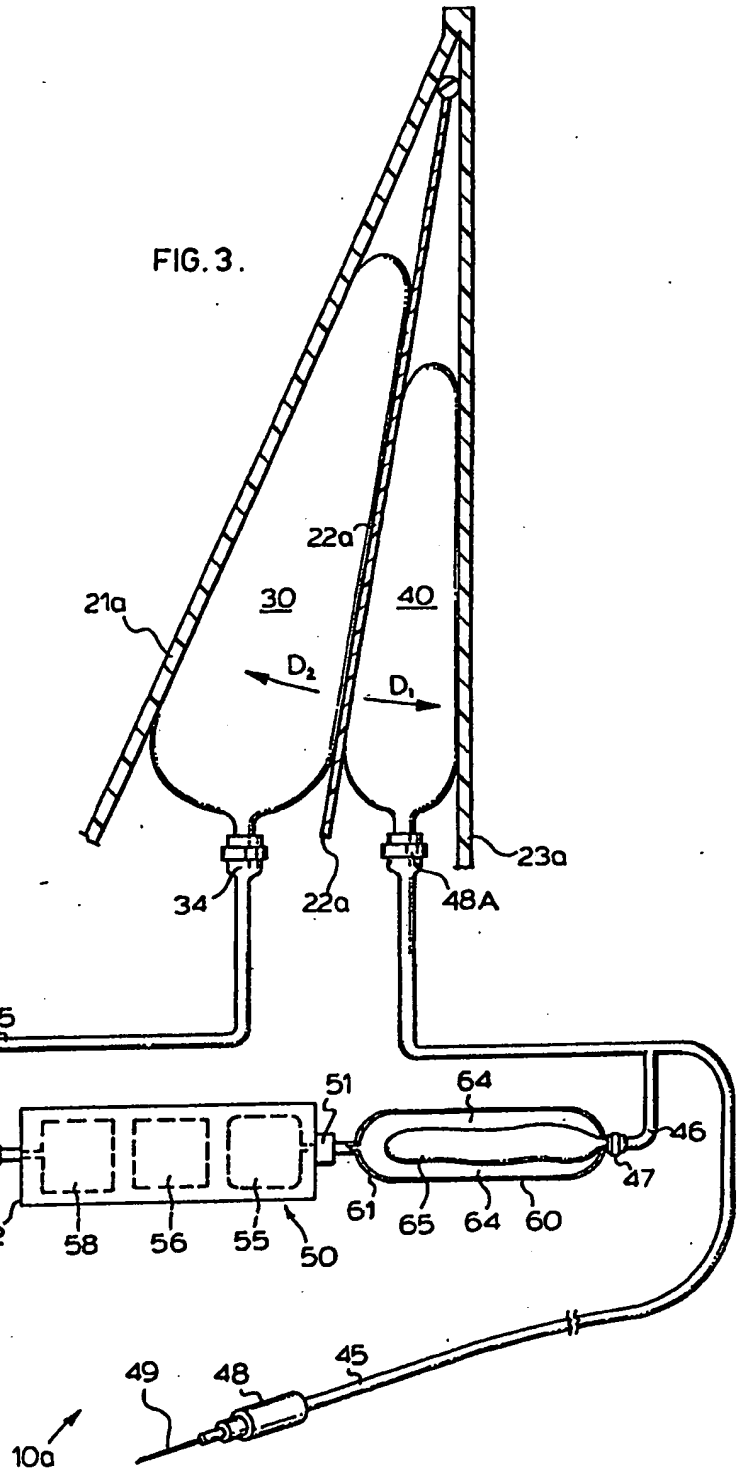

21a
22a
30
40
D_2
D_1
23a
34
22a
48A
35
36
51
64
46
47
52
58
56
55
50
61
65
64
60
49
48
45
10a

FIG.4.

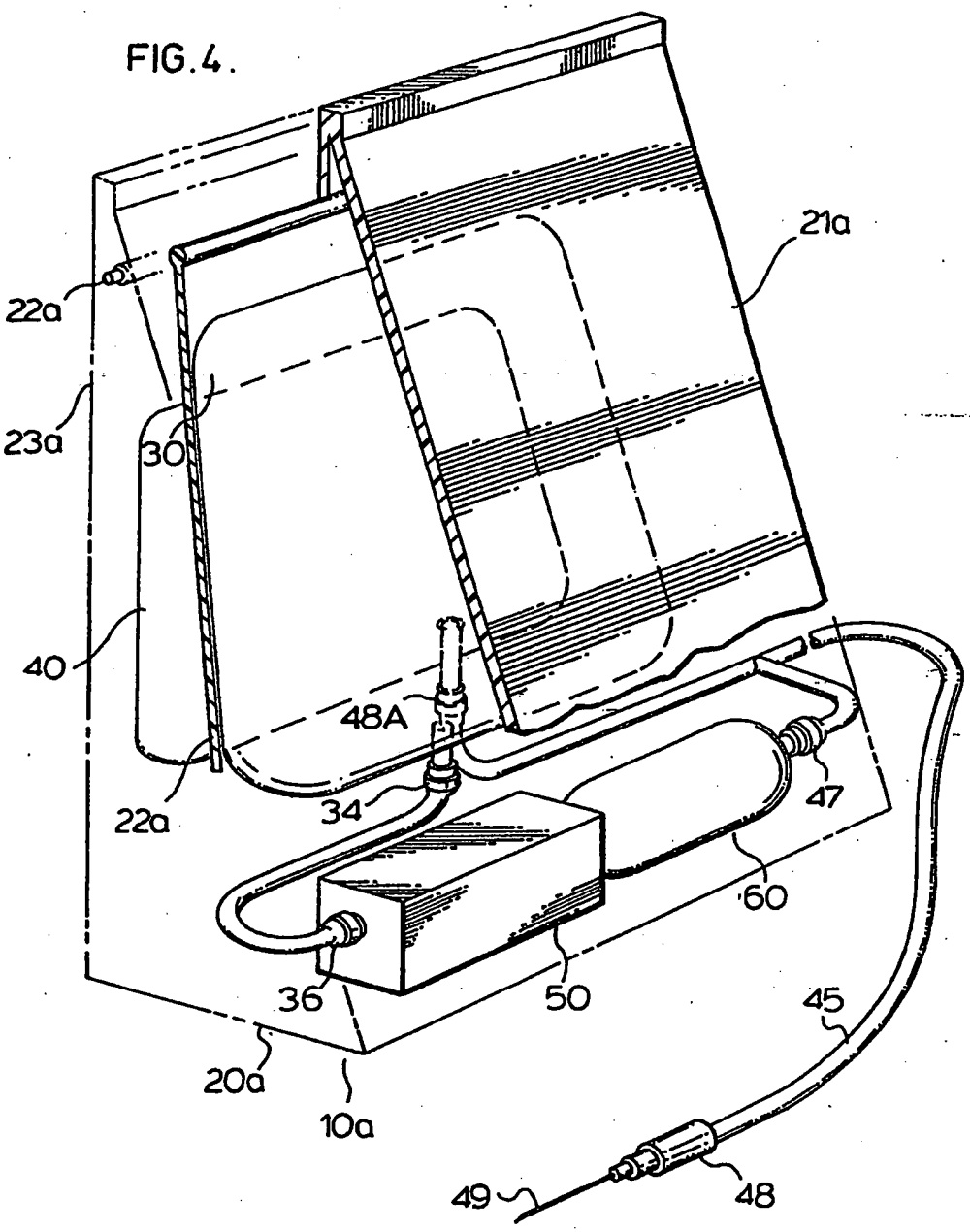


FIG.5.

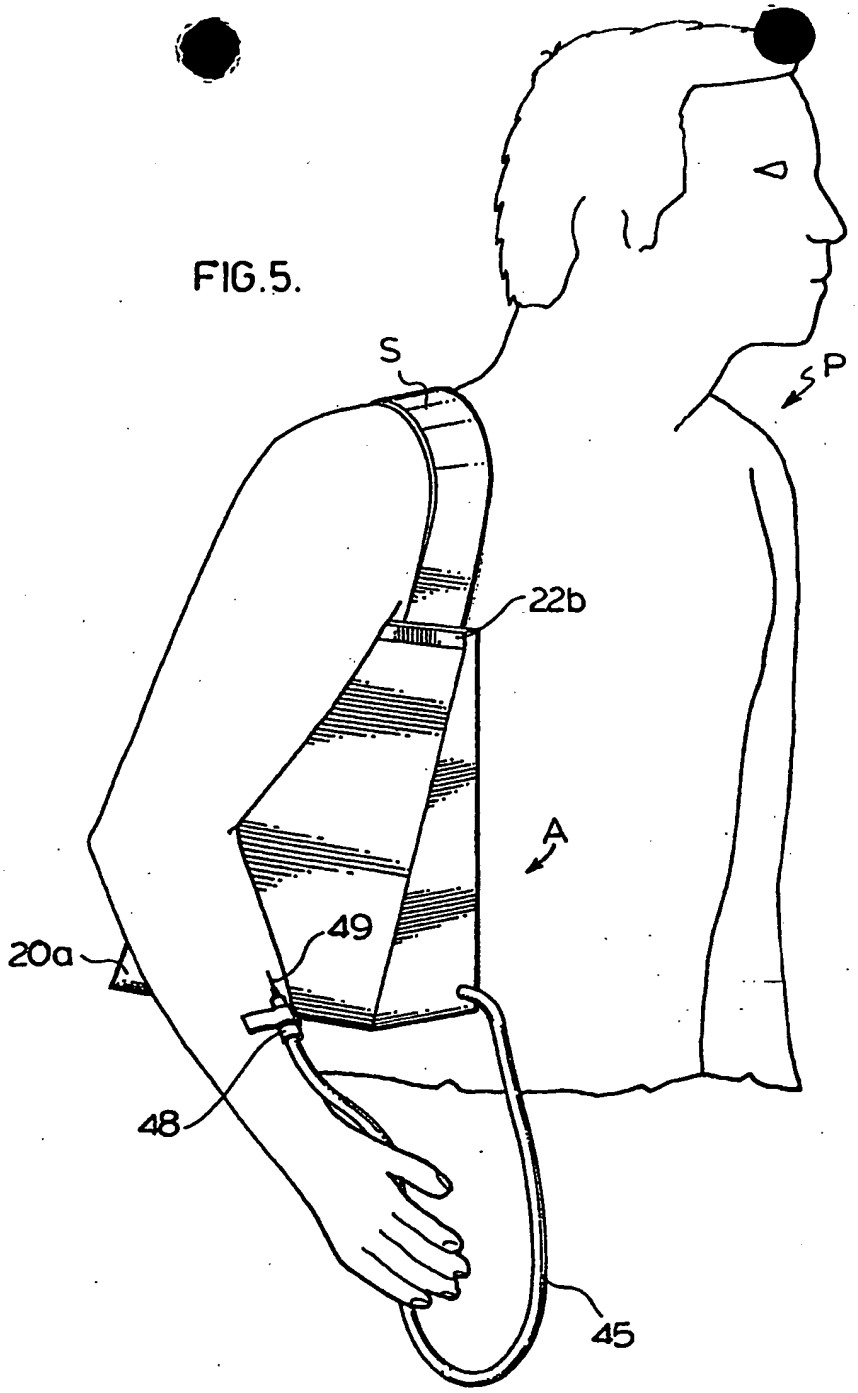
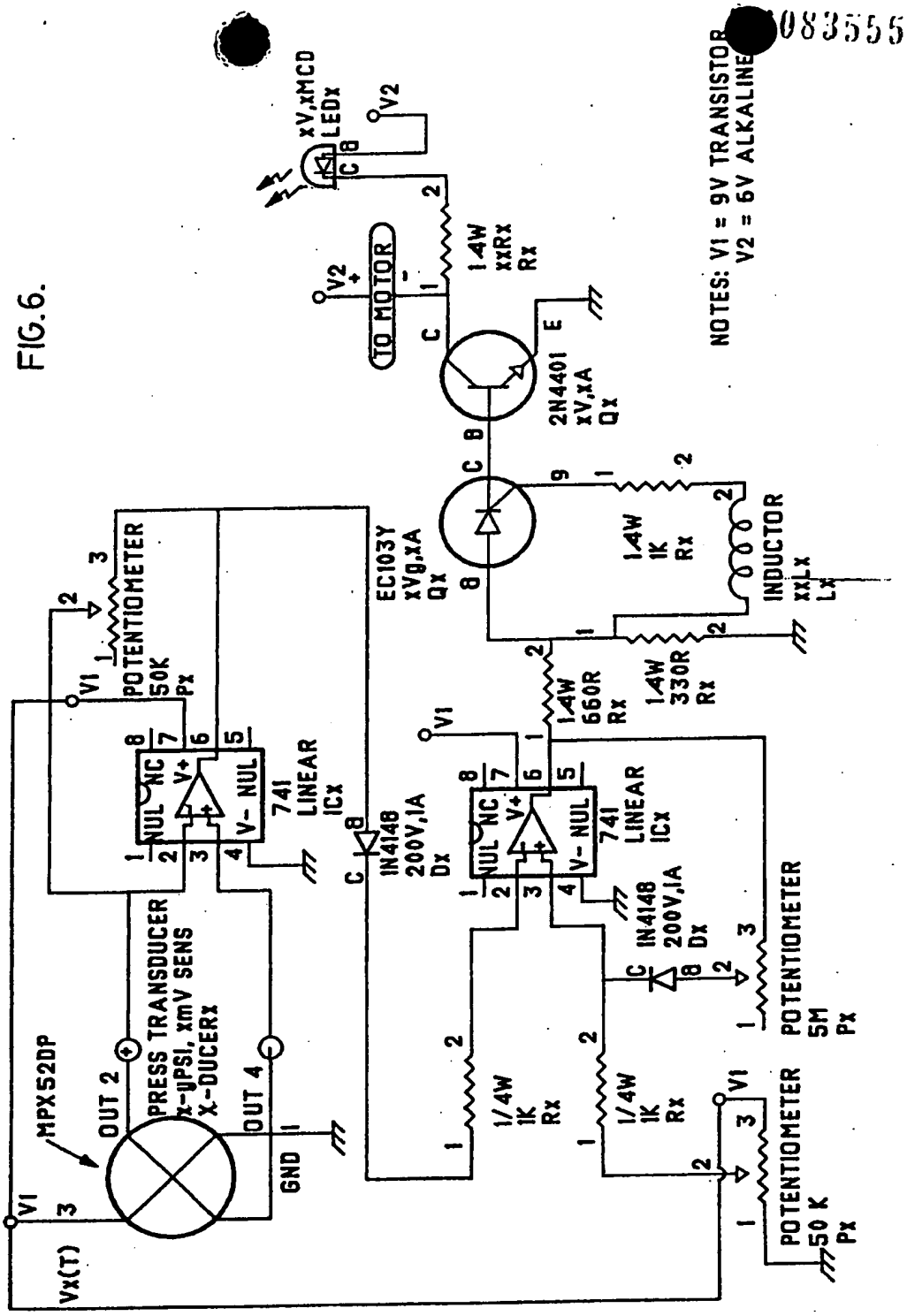
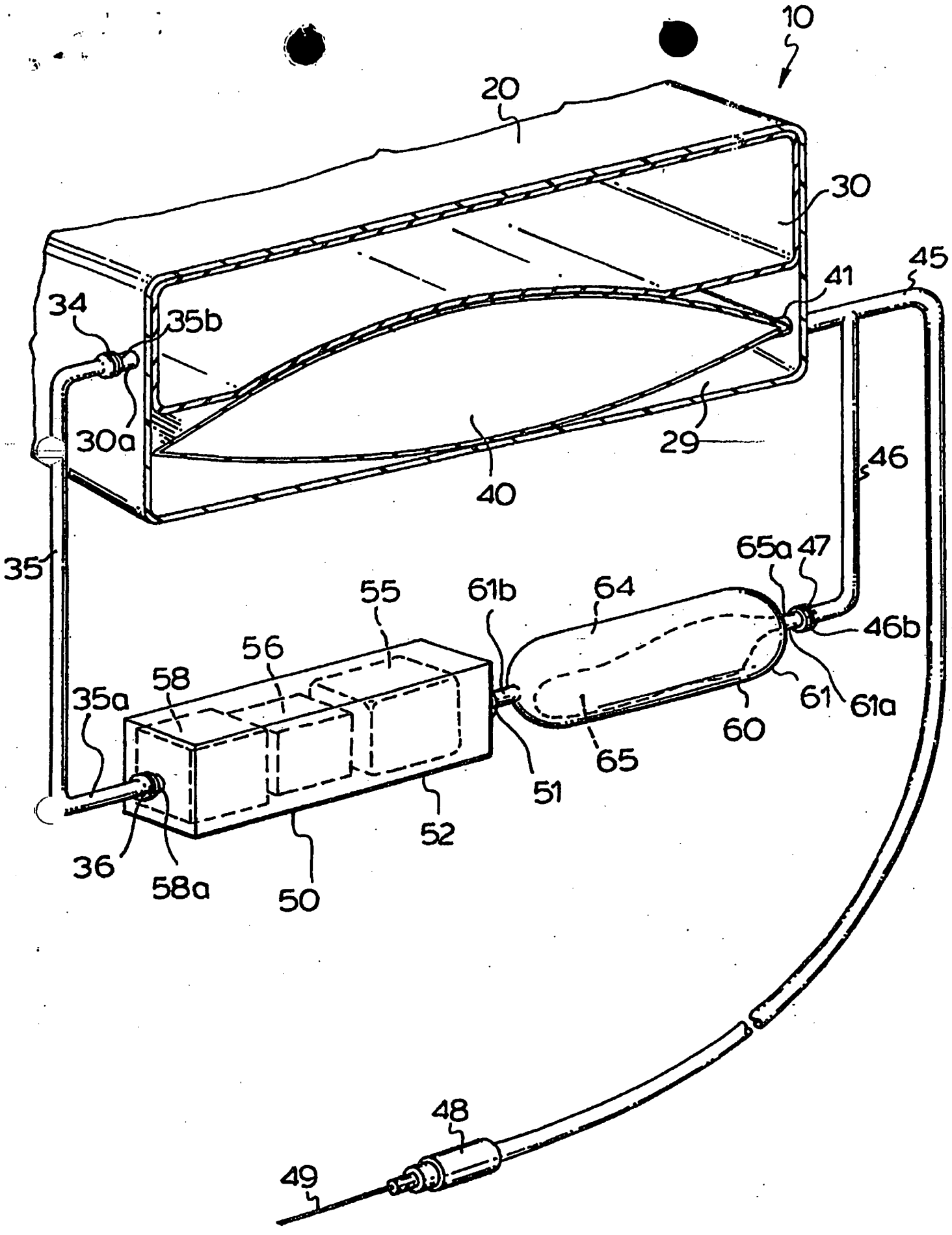


FIG.6.


NOTES: V1 = 9V TRANSISTOR
V2 = 6V ALKALINE
xV,xMCD LEDx
V2
1.4W xxRx Rx
TO MOTOR
2N4401 xV,xA Qx
EC103Y xVg,xA Qx
1.4W 1K Rx
INDUCTOR xxLx Lx
1.4W 660R Rx
1.4W 330R Rx
POTENTIOMETER 50K Px
741 LINEAR ICx
IN4148 200V,1A Dx
PRESS TRANSDUCER x-yPSI, xmV SENS X-DUCERx
MPX52DP
OUT 2
OUT 4
GND
1/4W 1K Rx
POTENTIOMETER 5M Px
POTENTIOMETER 50 K Px
Vx(T)
V1


10
20
30
45
41
34
35b
30a
29
40
46
35
65a
47
55
61b
64
46b
56
58
35a
61
61a
60
65
51
52
36
58a
50
48
49